

regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

[42 FR 14658, Mar. 15, 1977, as amended at 48 FR 48457, 48459, Oct. 19, 1983]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 186.1093 Sulfamic acid.

(a) Sulfamic acid ($\text{H}_3\text{NO}_3\text{S}$, CAS Reg. No. 5329-14-6) is a white crystalline solid manufactured from urea, sulfur trioxide, and sulfuric acid. It is soluble and highly ionized in water.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect food ingredient with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the current good manufacturing practice of using this ingredient in the manufacture of paper and paperboard that contact food.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 29954, July 9, 1982]

§ 186.1256 Clay (kaolin).

(a) Clay (kaolin) $\text{Al}_2\text{O}_3 \cdot 2\text{SiO}_2 \cdot n\text{H}_2\text{O}$, CAS Reg. No. 1332-58-7) consists of hydrated aluminum silicate. The commercial products of clay (kaolin) contain varying quantities of alkalies and alkaline earths. Clay (kaolin) is a white to yellowish or grayish fine powder. There are at least three different minerals, kaolinite, dickite, and nacrite, classified as kaolin. Kaolinite or china clay is whiter, less contaminated with extraneous minerals, and less plastic in water.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in the manufacture of paper and paperboard that contact food.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[47 FR 43367, Oct. 1, 1982]

§ 186.1275 Dextrans.

(a) Dextrans (CAS Reg. No. 9004-54-0) are high molecular weight polysaccharides produced by bacterial fermentation of sucrose. Commercially available dextrans are synthesized from sucrose by *Leuconostoc mesenteroides* strain NRRL B-512(F). Partial depolymerization and purification of the fermented mixture shall produce a product that is free of viable microorganisms.

(b) The ingredient is used or intended for use as a constituent of food-contact surfaces.

(c) The ingredient is used at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 29288, July 7, 1978, as amended at 48 FR 48457, Oct. 19, 1983]

§ 186.1300 Ferric oxide.

(a) Ferric oxide (iron (III) oxide, Fe_2O_3 , CAS Reg. No. 1309-37-1) occurs naturally as the mineral hematite. It may be prepared synthetically by heating brown iron hydroxide oxide. The product is red-brown to black trigonal crystals.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of paper and paperboard used for food packaging.

§ 186.1316

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16867, May 12, 1988; 53 FR 20939, June 7, 1988]

§ 186.1316 Formic acid.

(a) Formic acid (CH_2O_2 , CAS Reg. No. 64-18-6) is also referred to as methanoic acid or hydrogen carboxylic acid. It occurs naturally in some insects and is contained in the free acid state in a number of plants. Formic acid is prepared by the reaction of sodium formate with sulfuric acid and is isolated by distillation.

(b) Formic acid is used as a constituent of paper and paperboard used for food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for formic acid different from the uses established in this section do not exist or have been waived.

[45 FR 22915, Apr. 4, 1980]

§ 186.1374 Iron oxides.

(a) Iron oxides (oxides of iron, CAS Reg. No. 97705-33-85) are undefined mixtures of iron (II) oxide (CAS Reg. No. 1345-25-1, black cubic crystals) and iron (III) oxide (CAS Reg. No. 1309-37-1, red-brown to black trigonal crystals).

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of paper and paperboard used for food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in

21 CFR Ch. I (4-1-04 Edition)

this section do not exist or have been waived.

[53 FR 16867, May 12, 1988; 53 FR 20939, June 7, 1988]

§ 186.1551 Hydrogenated fish oil.

(a) Hydrogenated fish oil (CAS Reg. No. 91078-95-4) is a class of oils produced by partial hydrogenation of oils expressed from fish, primarily menhaden, and secondarily herring or tuna. Hydrogenation of fish oils uses catalysts composed of either elemental nickel, elemental copper, or a mixture of these elements. The crude hydrogenated fish oil is further processed by alkali refining, bleaching, and deodorization by steam stripping.

(b) Hydrogenation of fish oils results in a final product with a melting point greater than 32 °C as determined by Section Cc 1-25, Official and Tentative Methods of the American Oil Chemists' Society method (reapproved 1973) or equivalent. The product has an approximate fatty acid composition of 30 to 45 percent saturated fatty acids, 40 to 55 percent monoenoic fatty acids, 7 to 15 percent dienoic fatty acids, 3 to 10 percent trienoic fatty acids, and less than 2 percent tetraenoic or higher polyenoic fatty acids. The approximate percentages of total fatty acids by carbon chain length are 15 to 30 percent each of C_{16} , C_{18} , C_{20} , C_{22} , less than 10 percent C_{14} or lower carbon chain length, and less than 1 percent C_{24} or higher carbon chain length fatty acids.

(c) The ingredient is used as a constituent of cotton and cotton fabrics used for dry food packaging.

(d) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(e) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[44 FR 28323, May 15, 1979, as amended at 49 FR 5614, Feb. 14, 1984; 58 FR 17099, Apr. 1, 1993]

§ 186.1555 Japan wax.

(a) Japan wax (CAS Reg. No. 8001-39-6), also known as Japan tallow or sumac wax, is a pale yellow vegetable tallow, containing glycerides of the C_{19} - C_{23} dibasic acids and a high content